REMARKS / ARGUMENTS

1. The Amendments to the Claims

Before this Amendment, claims 1, 2, 5-11, 26-31 and 47-50 were pending. Upon entry of the present amendments, claims 47-50 and 66-68 will be pending and under active consideration. Claims 1, 2, 5-11, and 26-31 have been canceled without prejudice. The Applicant expressly reserves all rights to prosecute claims drawn to any subject matter removed by claim cancellation or by claim amendment made herein in a subsequent continuation application.

Claims 47, 48 and 50 have been amended to more particularly point out and distinctly claim the subject matter that the Applicant regards as his invention. New claims 66-68 have been added. No new matter is added by these amendments, and they are believed to place the claims in condition for allowance. The subject matter of the amended claims is fully supported in the specification and original claims as filed.

Claim 47 (and claim 49 depending therefrom) has been amended to recite a recombinant DNA comprising said DNA selected from the group consisting of:

a) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 3 wherein the protein elicits an immune response against *E. canis*;

b) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 5 wherein the protein elicits an immune response against *E. canis*;

c) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 7 wherein the protein elicits an immune response against *E. canis*;

d) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 9 wherein the protein elicits an immune response against *E. canis*; and

e) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 11 wherein the protein elicits an immune response against *E. canis*.

Support for the amendment to claim 47 is found in the specification at page 5, line 19 to page 6, line 29; page 7, line 1 to page 8, line 15; page 9, line 5 to page 10, line 11; and page 10, line 18 to page 12, line 20.

Claim 48 has been amended to recite a vector capable of expressing a recombinant DNA comprising:

a) a recombinant DNA inserted into said vector such that a recombinant protein is expressed when said vector is provided in an appropriate host wherein said DNA is selected from the group consisting of:

i) a recombinant DNA sequence that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 3 wherein the protein elicits an immune response against *E. canis*;

ii) a recombinant DNA sequence that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 5 wherein the protein elicits an immune response against *E. canis*;

iii) a recombinant DNA sequence that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 7 wherein the protein elicits an immune response against *E. canis*;

iv) a recombinant DNA sequence that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 9 wherein the protein elicits an immune response against *E. canis*; and

v) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 11 wherein the protein elicits an immune response against *E. canis*.

Support for the amendment to claim 48 is found in the specification (as above for claim 47) at page 5, line 19 to page 6, line 29; page 7, line 1 to page 8, line 15; page 9, line 5 to page 10, line 11; and page 10, line 18 to page 12, line 20.

Claim 50 has been amended to recite a vector capable of expressing a recombinant DNA comprising:

a) a recombinant DNA inserted into said vector such that a recombinant protein is expressed when said vector is provided in an appropriate host wherein said DNA is selected from the group consisting of:

i) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 3 wherein the protein elicits an immune response against *E. canis*;

ii) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 5 wherein the protein elicits an immune response against *E. canis*;

iii) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 7 wherein the protein elicits an immune response against *E. canis*;

iv) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 9 wherein the protein elicits an immune response against *E. canis*; and

v) a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NO. 11 wherein the protein elicits an immune response against *E. canis*.

Support for the amendment to claim 50 is found in the specification (as above for claims 47 and 48) at page 5, line 19 to page 6, line 29; page 7, line 1 to page 8, line 15; page 9, line 5 to page 10, line 11; and page 10, line 18 to page 12, line 20.

New claims 66-68 have been added. Support for new claims 66-68 is found in the specification (as above for claims 47, 48 and 50) at page 5, line 19 to page 6, line 29; page 7, line 1 to page 8, line 15; page 9, line 5 to page 10, line 11; and page 10, line 18 to page 12, line 20.

2. Double Patenting

At page 3 of the Office Action, claims 10 and 11 are objected to under 37 CFR 1.75 as allegedly being substantial duplicates of claim 6. While the Applicant does not in any way agree with this objection, merely to advance prosecution and obtain coverage for certain embodiments of the invention, claims 10 and 11 have been canceled without prejudice. The Applicant expressly reserves all rights to argue against the rationale of the rejection and to prosecute claims drawn to any subject matter removed by claim cancellation or by claim amendment made herein in a subsequent continuation application.

Not withstanding their reservation, since claims 10 and 11 have been canceled without prejudice, the rejection with respect to these claims is moot. It is respectfully requested that the rejection to claims 10-11 on the grounds of double-patenting be reconsidered and withdrawn.

3. The Rejections

a. Examiner's Rejections Under 35 U.S.C. § 112 (First Paragraph) Should Be Withdrawn

At page 4 of the Office Action, claims 5-11 and 26-31 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention. At page 8 of the Office Action, claims 9 and 29 have been further rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the Applicant does not in any way agree with these rejections, merely to advance prosecution and obtain coverage for certain embodiments of the invention, claims 5-11 and 26-31 have been canceled without prejudice. The Applicant expressly reserves all rights to argue against the rationale of the rejection and to prosecute claims drawn to any subject matter removed by claim cancellation or by claim amendment made herein in a subsequent continuation application.

Not withstanding their reservation, since claims 5-11 and 26-31 have been canceled without prejudice, the rejection with respect to these claims is moot. It is respectfully submitted that the rejection of claims 5-11 and 26-31 under 35 U.S.C. §112, first paragraph, is thus overcome. Reconsideration and withdrawal of the rejection of claims 5-11 and 26-31 under 35 U.S.C. §112, first paragraph, is respectfully requested.

b. Examiner's Rejections Under 35 U.S.C. § 102(b) Should Be Withdrawn

At page 10 of the Office Action, claims 1, 2 and 47-50 were rejected under 35 U.S.C. 102(b), as being anticipated by Lewis *et al.* (1994, Sequence, organization, and evolution of the A+T region of *Drosophila melanogaster* mitochondrial DNA. Mol. Biol. Evol. 11: 523-538). While the Applicant does not in any way agree with this rejection, merely to advance prosecution and obtain coverage for certain embodiments of the invention, claims 47 (and 49 depending therefrom), 48 and 50 have been amended, new claims 66-68 have been added, and claims 1 and 2 have been canceled without prejudice. The Applicant expressly reserves all rights to argue against the rationale of the rejection and to prosecute claims drawn to any subject matter removed by claim cancellation or by claim amendment made herein in a subsequent continuation application.

Not withstanding their reservation, since claims 1 and 2 have been canceled without prejudice, the rejection with respect to these claims is moot. With respect to amended claims

47 (and 49 depending therefrom), 48 and 50, the Applicant respectfully disagrees with the rejection.

As amended, claims 47-50 now recite a recombinant DNA (or recombinant DNA sequence) that encodes a protein having an amino acid sequence as shown in SEQ. ID. NOs . 3, 5, 7, 9 or 11, wherein the protein elicits an immune response against *E. canis*.

Lewis *et al.* does not disclose a recombinant DNA that encodes a protein having an amino acid sequence as shown in SEQ. ID. NOS. 3, 5, 7, 9 or 11 that elicits an immune response against *E. canis*. Moreover, the Examiner states that he "agree[s] that Lewis *et al.* fails to teach the use of the sequence [of Lewis *et al.*] as a vaccine or its ability to elicit a response to *E. canis*. . . ." (Office Action, page 11).

However, the Examiner also states that:

> . . . in evaluating the breadth of the claims in light of the teachings of the specification, Examiner is left to interpret the claims structurally to encompass any homologous sequence to that disclosed and claimed. The instant specification does not point to any specific sequence [that is] necessary nor required for eliciting an immune response. . . . The claims broadly encompass any polynucleotide sequence which encodes an amino acid sequence that can elicit an immune response and vectors capable of expressing said protein.

(Office Action, page 11, emphasis added).

The Applicant respectfully disagrees. The specific sequences recited in amended claims 47 (and 49 depending therefrom), 48 and 50, *i.e.*, SEQ ID NOs 3, 5, 7, 9 and 11, are specifically pointed out at page 5, line 19 to page 6, line 29 of the specification as sequences that can be used for eliciting an immune response against *E. canis*, and the use of the proteins encoded by SEQ ID NOs 3, 5, 7, 9 and 11 to elicit an immune response against *E. canis* is taught at page 7, line 1 to page 8, line 15; page 9, line 5 to page 10, line 11; and page 10, line 18 to page 12, line 20 of the specification.

The Applicant also respectfully draws the Examiner's attention to the Declaration of Yung-Fu Chang, Ph.D. Under 37 C.F.R. § 1.132, filed in connection with the present application on July 23, 2005 ("the Declaration"). The Declaration confirms what the instant

specification teaches, *i.e.*, that by using methods disclosed in the specification and routine methods known in the art, the proteins encoded by SEQ ID NOs 3, 5, 7, 9 and 11 can be used to elicit an immune response against *E. canis*. With respect to SEQ ID NOs 5 (ProA), 7 (ProB) and 9 (mmpA), Dr. Chang declares that this has been experimentally confirmed by others.

With respect to SEQ ID NO: 9, at paragraph no. 8 of the Declaration, Dr. Chang declares that Teng et al. (2003a), using the methods disclosed in the instant specification and routine methods known in the art, confirmed that a putative *E. canis* vaccine can be produced using one of the ORFs disclosed in the instant specification, namely, mmpA (erlichial morula membrane protein A) (SEQ ID NO: 9). Furthermore, the recombinant protein encoded by the mmpA ORF was recognized by sera from dogs that were either naturally or experimentally infected with *E. canis*.

With respect to SEQ ID NOs: 5 and 7, at paragraph no. 9 of the Declaration, Dr. Chang declares that Teng et al. (2003b), using methods disclosed in the instant specification and routine methods known in the art, confirmed that two additional ORFs disclosed in the instant specification, ProA (SEQ ID NO: 5) and ProB (SEQ ID NO: 7), code for proteins that are expressed in *E. canis* and that can be used in making an *E. canis* vaccine. Teng et al. (2003b) demonstrated that the ProA and ProB ORFs are transcribed and translated into ProA and ProB proteins, respectively. Furthermore, both recombinant protein antigens, ProA and ProB, were recognized by sera from dogs that were either naturally or experimentally infected with *E. canis*.

At paragraph no. 10 of the Declaration, Dr. Chang declares that using the methods disclosed in the instant specification and routine methods known in the art, Teng et al. 2003a and Teng et al. 2003b confirmed that the MmpA, ProA and ProB proteins contain immunogenic epitopes, and demonstrated clear connections between the MmpA, ProA and ProB ORFs and protein epitopes that are recognized by the antisera from dogs infected with *E. canis*. The results also demonstrated that the encoded proteins from the MmpA, ProA and ProB ORFs can serve as potential vaccines for *E. canis* infection.

In summary, the Declaration confirms that the instant specification has identified and

described specific sequences, SEQ ID NOs 3, 5, 7, 9 and 11, for eliciting an immune response against *E. canis*. The Applicant therefore maintains that, contrary to the statement of the Examiner at page 11 of the Office Action, the specification does point to specific sequences, SEQ ID NOs 3, 5, 7, 9 and 11, that are necessary or required for eliciting an immune response against *E. canis*. Furthermore, the teachings of the specification regarding this issue have been confirmed, as Dr. Chang states in the Declaration. Finally, as currently amended, claims 47-50 do not broadly encompass any polynucleotide sequence which encodes an amino acid sequence that can elicit an immune response and vectors capable of expressing said protein (see Office Action, page 11).

As previously set forth by the Applicant at page 21 of the Amendment and Response under 37 C.F.R. §1.111 filed on July 23, 2005, if the Examiner relies upon the theory of inherency, then the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic, *i.e.*, eliciting an immune response against *E. canis*, necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990), emphasis added. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981), emphasis added.

Lewis *et al.* does not teach a DNA that encodes a protein having an amino acid sequence as shown in SEQ ID NOs 3, 5, 7, 9 or 11 wherein the protein elicits an immune response against *E. canis*, nor does this allegedly inherent characteristic necessarily flow from the teachings of Lewis *et al.*

In summary, Lewis *et al.* does not anticipate claims 47 (and 49 depending therefrom), 48 and 50, as presently amended, and the Examiner has not provided any reasonable basis in fact and/or technical reasoning to support a rejection for anticipation by inherency.

It is respectfully submitted that the rejection under 35 U.S.C. 102(b) for anticipation is thus overcome. Reconsideration and withdrawal of the rejection of claims 1, 2 and 47-50 as being anticipated by Lewis *et al.* are therefore respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicant believes that the application is in good and proper condition for allowance. Early notification to that effect is earnestly solicited. If the Examiner feels that a telephone call would expedite the consideration of the application, the Examiner is invited to call the undersigned attorney at (315) 425-9000.

If there are any other fees due in connection with the filing of this Amendment or accompanying papers, please charge the fees to Wall Marjama and Bilinski LLP's Deposit Account No. **50-0289**. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to the Deposit Account.

Respectfully submitted,

Date: December 19, 2005

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Enclosures